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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/346,794 | 07/02/99 | SNUTCH T | NMEDP001-2 |

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| EXAMINER | |
|---|---|
| BASI,N | |
| ART UNIT | PAPER NUMBER |
| 1646 | 17 |

DATE MAILED: 10/10/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/346794 | Applicant(s) Shukla et al |
|---|---|---|
| | Examiner Nirmal S. Basi | Group Art Unit 1646 |

*—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—*

**Period for Response**

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

☒ Responsive to communication(s) filed on 7/23/01.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

**Disposition of Claims**

☒ Claim(s) 25 - 33 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☐ Claim(s)____ is/are allowed.

☒ Claim(s) 25-33 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119 (a)-(d)**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

**Attachment(s)**

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13

☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other____

**Office Action Summary**

## DETAILED ACTION

1. Amendment filed 7/23/01 (paper number 16) and Declaration filed 7/23/01 (paper number 150) have been entered.

### Claim Rejection, 35 U.S.C. 112, second paragraph

3. Claim 25-27 and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 and dependent claims 26-27 are indefinite because the preamble recites "A method of identifying compound which behaves as an agonist for a T-type mammalian calcium channel, but the claim does not state how the goal of the preamble is achieved. It is not clear what activity is determined and how an agonist is identified. An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved. In instant case steps 2 and 3 are not clearly defined.

Claim 31 is indefinite because it is not what determines if a compound is an agonist or antagonist and how the conclusion that what was stated in the preamble was achieved.

Claim 32 is indefinite because it is not clear how the determination of competitive binding determines if a compound is an agonist or antagonist.

Claim 33 is indefinite because it is not clear how the label is provides and what are "equilibrium binding measurements", so as to allow the metes and bounds of the claim to be determined. Further it is not clear how "equilibrium binding measurements" determine if a compound is an agonist or antagonist.

Applicant arguments and the disclosure of Terrance Snutch have been fully considered. Applicant argues, "It is both described in the specification and known in the art that T-type calcium channels are associated with a multiplicity of conditions, and that blocking the activity of these channels or activating them will have, therefore, an effect on these conditions. Terrance Snutch discloses T-type activity is associated with a number of cardiac conditions including pacemaker activity, cardiac hypertrophy hypertension, abnormal T-type calcium function is also associated with neurological disease, impaired fertility and agonists and antagonists of T-type calcium channels are useful in treating these conditions. Snutch also states the "particular T-type calcium channel involved I a particular condition may depend on its tissue distribution". The specification discloses, "The present invention relates to novel mammalian (including human) calcium channel compositions, and to the expression of these compositions in cell lines for use in evaluating calcium channel function and the behavior of compositions which modulate calcium channel function". The response of the Applicant nor the specification disclose the function of the novel α subunits ($\alpha_{1G}$, $\alpha_{1H}$ and $\alpha_{1I}$ subunits) which relate to the present invention.

***Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph***

The following is a quotation of 35 U.S.C. 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 25-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention. Applicant has asserted utilities for the "$\alpha_1$ subunit of a mammalian T-type calcium channel".

For example, the specification at page 1 asserts that, "The present invention relates to novel mammalian (including human) calcium channel compositions, and to the expression of these compositions in cell lines for use in evaluating calcium channel function and behavior of compositions which modulate calcium channel function". Further stated is, "In addition to the variety of normal physiological functions mediated by calcium channels, they are also implicated in a number of human disorders". The specification, in Table 5, discloses the electrophysical and pharmacological properties of known $\alpha_1$ subunits of calcium channels which have been "cloned to date". The $\alpha_1$ subunits are associated with calcium channels of the type L, N, and P/Q. The present invention, "provides sequences for novel mammalian calcium channel subunits of T-type calcium channels", which are labeled as $\alpha_{1G}$, $\alpha_{1H}$ and $\alpha_{1I}$ subunits". The specification states that "these subunits, either alone or assembled with other proteins, can produce functional calcium channels, which can be evaluated in model cell lines to determine the properties of the channels containing the subunits of the invention. Theses cell lines can be used to evaluate the effects of pharmaceuticals and /or toxic substances on calcium channels incorporating $\alpha_{1G}$, $\alpha_{1H}$ and $\alpha_{1I}$ subunits" (page 7) . The specification discloses polynucleotide encoding "$\alpha_1$ subunit" may be useful as probes in screening human cDNA libraries for genes encoding these novel calcium channel subunits, the $\alpha_1$ subunit may be used to generate antibodies, cell lines expressing $\alpha_1$ subunit may be used to evaluate compounds as pharmacological modifiers of the function of novel calcium channel subunits, (page 8). Further disclosed novel calcium channel subunits may be associated with a human genetic disease including, but not limited to; epilepsy, migraine, ataxia, hypertension, arrhythmia, angina, depression, small lung

carcinoma. Lambert-Eaton syndrome, characterization of such associations and ultimately diagnosis of associated diseases can be carried out with probes which bind to the wild-type or defective forms of the novel calcium channels (page 9).

The utilities asserted by Applicant are not substantial or specific. Neither the specification nor the art of record disclose any disease states treatable by the novel polynucleotides, of instant invention, or polypeptides encoded by them. Similarly, neither the specification nor the art of record disclose any instances where blocking any effects of said polynucleotides or polypeptides encoded by them reduces the effect of a disease state. Thus the corresponding asserted utilities are essentially methods of treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use especially when the complete sequence of the claimed invention is not known. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the disclosed polynucleotides or the polypeptides encoded by them, further experimentation is necessary to attribute a utility to the claimed polynucleotides and encoded polypeptides. See Brenner v. Manson, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Since the utilities asserted by Applicant for polynucleotide and

polypeptide of instant application are not substantial or specific, then it follows that the method of claim 21 (method of identifying compounds capable of acting a s agonists or antagonists for T-type mammalian calcium channels), also has no utility. Similarly, agonists and antagonists identified by said method have no utility.

8. Claims 25-33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Further, even if one of skill in the art were enabled to use the instant method, one would not be enabled to practice the method as broadly claimed because the general structural attributes definitive of $\alpha_1$-subunit for T-type calcium channels are not taught in the specification, nor known in the art (also see rejection under 35 U.S.C. 112, second paragraph above). One would be enabled to make T-type channels using only the instant $\alpha_{1G}$, $\alpha_{1H}$ or $\alpha_{1I}$ subunits. No claim is allowed.

**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
October 9, 2001

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600